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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,025	11/21/2001	Junichi Nakai	216339US0	9580
7590 11/05/2003				
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT 1755 JEFFERSON DAVIS HIGHWAY FOURTH FLOOR ARLINGTON, VA 22202			EXAMINER SNEDDEN, SHERIDAN	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/989,025	NAKAI, JUNICHI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sheridan K Snedden	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 1-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-64 is/are rejected.
- 7) ☐ Claim(s) 34-64 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3/12/02</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendment of claims 29 and 33, filed 5 February 2002 is acknowledged.  
Claims 1-64 are pending.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 2, drawn to a method of producing a biosensor, classified in class 435, subclass 69.1.
  - II. Claims 3-33, drawn to a biosensor protein, classified in class 530, subclass 350.
  - III. Claims 34-64, drawn to a gene encoding a biosensor protein, classified in class 536, subclass 23.4.

3. The inventions are distinct, each from the other because of the following reasons:

Invention I discloses a method for making the product of invention II and are thus related. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the protein product can be made by another and materially different process, such as by synthetic peptide synthesis.

Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the nucleic acids of

invention III may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, the inventions are patentably distinct.

The nucleic acids of invention III are related to the protein of invention II by virtue of encoding same. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation. Thus, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Vincent Shier on October 1, 2003 a provisional election was made with traverse to prosecute the invention of III, claims 34-64. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

#### ***Specification and Claim Objections***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

Art Unit: 1653

this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant is reminded of the following:

*§1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.*

(a) Nucleotide and/or amino acid sequences as used in § 1.821 through 1.825 are interpreted to mean an **unbranched sequence of four or more amino acids** or an **unbranched sequence of ten or more nucleotides**. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section.

(d) Where the **description** or **claims** of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, **reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:"** in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant's attention is directed to the specification at pages 10, 12, 19, 20, 37, 42, 43, 47, 50, 51, 57, 62, 63, and 64. (see also claims 29 and 33). Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

6. Claims 34-64 objected to under 37 CFR 1.75(c) as being in improper form because they depend from non-elected claim 3-33.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-64 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term “gene” in claims 34-64 is used by the claim to mean “nucleic acid molecules encoding an artificial fusion protein”, while the accepted meaning is “region of DNA that controls a discrete hereditary characteristic and includes exons, introns and noncoding regulatory DNA sequences.” The term is indefinite because the specification does not clearly redefine the term.

9. Claims 36-47 and 50-64 are indefinite for depending on non-elected claims which are themselves indefinite. Claims 5-16 and 19-33 refer to positions of a sequence that is not identified by the claims. For example, it cannot be determined what is position 148 or Xth without a reference sequence present in the claim. Reference to an amino acid sequence by SEQ ID NO: is required.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1653

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 34-46, 47-59, and 61 rejected under 35 U.S.C. 102(e) as being anticipated by Persechini (US 6376257). Persechini teaches a green fluorescent protein (GFP) covalently attached via a linker sequence to the calmodulin binding domain of myosin light chain kinase (see column 9, lines 23-47). Claim 1 recites a fusion protein comprising a first GFP sequence, the calmodulin binding domain and a second GFP sequence. Two GFP variants are used in the above fusion protein. The specific positions recited claims are indefinite and thus the reference teaches the same fusion protein. Thus, the reference anticipates the claimed invention.

12. Claims 34-46, 47-59, and 61 rejected under 35 U.S.C. 102(b) as being anticipated by Baird *et al.* (IDS). Baird *et al.* teaches the insertion of calmodulin at Tyr-145 of yellow mutant of GFP. The specific positions recited claims are indefinite and thus the reference teaches the same fusion protein. Thus, the reference anticipates the claimed invention.

***Conclusion***

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843.

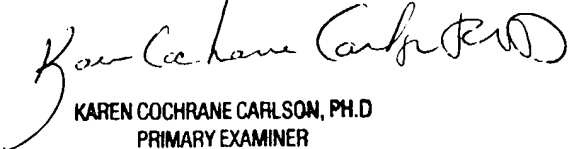
The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 746-3975.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS  
October 22, 2003

SKS

  
KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER